



## DEPARTMENT OF COMMERCE

### United States Patent and Trademark Office

#### Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Deposit of Biological Materials

**AGENCY:** United States Patent and Trademark Office, Department of Commerce.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651-0022 Deposit of Biological Materials. The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

**DATES:** To ensure consideration, comments regarding this information collection must be received on or before [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Email:* [InformationCollection@uspto.gov](mailto:InformationCollection@uspto.gov). Include "0651-0022 comment" in the subject line of the message.

- *Federal Rulemaking Portal*: <http://www.regulations.gov>.
- *Mail*: Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Parikha Mehta, Senior Legal Advisor, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450; by telephone at 571-272-3248; or by email at [parikha.mehta@uspto.gov](mailto:parikha.mehta@uspto.gov) with “0651-0022 comment” in the subject line. Additional information about this information collection is also available at <http://www.reginfo.gov> under “Information Collection Review.”

**SUPPLEMENTARY INFORMATION:**

**I. Abstract**

This collection covers information from patent applicants who seek to deposit biological materials as part of a patent application according to 37 CFR 1.801-1.809. The information collected from such patent applicants consists of information and documentation demonstrating the applicant’s compliance with regulatory requirements, as well as information regarding the biological sample after it is deposited. This collection also covers applications from institutions that wish to be recognized by the USPTO as a suitable depository to receive deposits for patent application purposes. The information collection requirements for these actions are separate, as further discussed below.

**A. Deposits of Biological Materials**

The deposit of biological materials as part of a patent application is authorized by 35 U.S.C. 2(b)(2). The term “biological material” is defined in 37 CFR 1.801 as including material that is capable of self-replication, either directly or indirectly. When an invention involves a biological material, words and figures may not sufficiently describe how to make and use the invention in a reproducible manner as required by 35

U.S.C. 112. In such cases, the inventive biological material must be known and readily available to the public or can be made or isolated without undue experimentation (see 37 CFR 1.802). In order to satisfy the “known and readily available” requirement, the biological material may be deposited in a suitable depository that has been recognized as an International Depositary Authority (IDA) established under the Budapest Treaty per 37 CFR 1.803(a)(1), or any other depository recognized to be suitable by the USPTO per 37 CFR 1.803(a)(2). Under the authority of 35 U.S.C. § 2(b)(2), the deposit rules (37 CFR 1.801–1.809) set forth examining procedures and conditions of deposit which must be satisfied in the event a deposit is required.

In cases where a deposit of biological material that is capable of self-replication either directly or indirectly is made, and the deposit is not made under the Budapest Treaty, the USPTO collects information to determine whether the deposit meets the viability requirements of 37 CFR 1.807. This information includes a viability statement under 37 CFR 1.807, such statement identifying:

- (1) The name and address of the depository where the deposit was made,
- (2) The name and address of the depositor,
- (3) The date of the deposit,
- (4) The identity of the deposit and the accession number given by the depository,
- (5) The date of the viability test,
- (6) The procedures used to obtain a sample if the test was not done by the depository, and
- (7) A statement that the deposit is capable of reproduction.

A viability statement is not required when a deposit is made and accepted under the Budapest Treaty.

This collection also covers additional information that may be gathered by the USPTO after a biological material is deposited into the recognized depository. For example, depositors may be required to submit verification statements for biological

materials deposited after the effective filing date of a patent application or written notification that an acceptable deposit will be made. Occasionally a deposit may be lost, contaminated, or is not able to self-replicate, and a replacement or supplemental deposit needs to be made. This information collection includes a required written notification that the depositor must submit to the USPTO disclosing the particulars of such situation and request a certificate of correction by the USPTO authorizing a replacement or supplemental deposit.

There are no forms associated with the information collected by the USPTO in connection with the deposit of biological materials, however there are forms available under the Budapest Treaty for use with international depositories.

## **B. Depositories**

Institutions that wish to be recognized by the USPTO as a suitable depository to receive deposits for patent purposes, are required by 37 CFR 1.803(b) to make a request demonstrating that they are qualified to store and test the biological materials submitted to them under patent applications (see also MPEP 2405). This collection covers the information that a depository must submit to the USPTO when seeking recognition by the Office as a suitable depository under 37 CFR 1.803(a)(2). This information enables the USPTO to evaluate whether such a depository has internal practices (both technical and administrative) and the technical ability sufficient to protect the integrity of the biological materials being stored by U.S. patent applicants. This information includes:

- (1) The name and address of the depository seeking recognition under 37 CFR 1.803(a)(2),
- (2) Detailed information as to the capacity of the depository to comply with the requirements of 37 CFR 1.803(a)(2), including information on its legal status, scientific standing, staff, and facilities;
- (3) An indication that the depository intends to be available, for the purposes of deposit, to any depositor under these same conditions;

(4) Where the depository intends to accept for deposit only certain kinds of biological material, specify such kinds; and

(5) An indication of the amount of any fees that the depository will, upon acquiring the status of suitable depository under paragraph (a) (2) of this section, charge for storage, viability statements and furnishings of samples of the deposit.

This collection also includes additional information gathered by the USPTO that may be needed after a depository has been recognized by the USPTO under 37 CFR 1.803(a)(2), such as requests to handle additional types of biological materials other than the material originally recognized, and viability statements that depositories may submit on behalf of depositors for deposits tested at the depository and/or documentation proving the public has been notified about where to obtain samples. There is no application form associated with requests under 37 CFR 1.803(b) to become a recognized depository.

## **II. Method of Collection**

Electronically via the USPTO's patent electronic filing system, by mail or hand delivery to the USPTO.

## **III. Data**

*OMB Control Number:* 0651-0022.

*Forms:* No form associated for domestic depositories; Forms BP/1, BP/2, BP/3, BP/9 for use of international depositories under the Budapest Treaty.

- BP/1 (Statement in the Case of an Original Deposit (Rule 6.1))
- BP/2 (Statement in the Case of a New Deposit with the Same International Depository Authority (Rule 6.2))
- BP/3 (Statement in the Case of a New Deposit with Another International Depository Authority (Rule 6.2))
- BP/9 (Viability Statement (Rule 10.2) (International Form))

*Type of Review:* Extension and revision of a currently approved information collection.

*Affected Public:* Private sector.

*Respondent's Obligation:* Required to obtain or retain benefits.

*Estimated Number of Annual Respondents:* 3,301 respondents.

*Estimated Number of Annual Responses:* 3,301 responses.

*Estimated Time per Response:* The USPTO estimates that the responses in this information collection will take the public approximately between 1 hour and 5 hours to complete, depending on the complexity of the situation and item, to gather the necessary information, prepare the appropriate document(s), and submit the information to the USPTO.

*Estimated Total Annual Respondent Burden Hours:* 3,305 hours.

*Estimated Total Annual Respondent Hourly Cost Burden:* \$475,788.

**Table 1: Total Burden Hours and Hourly Costs to Private Sector Respondents**

Item No.	Item	Estimated Annual Respondents (a)	Responses per Respondent (b)	Estimated Annual Responses (a) x (b) = (c)	Estimated Time per Response (hours) (d)	Estimated Burden (hour/year) (c) x (d) = (e)	Rate <sup>1</sup> (\$/hour) (f)	Estimated Annual Respondent Cost Burden (e) x (f) = (g)
1	Deposited Materials	3,300	1	3,300	1	3,300	\$143.96	\$475,068
2	Request for Depository Approval	1	1	1	5	5	\$143.96	\$720
	<b>Totals</b>	<b>3,301</b>	<b>---</b>	<b>3,301</b>	<b>---</b>	<b>3,305</b>	<b>---</b>	<b>\$475,788</b>

*Estimated Total Annual Respondent Non-hourly Cost Burden:* \$9,259,809. There are no maintenance costs, record keeping costs, or filing fees associated with this information collection. However, the USPTO estimates that the total annual (non-hour) cost burden for this information collection, in the form of capital start-up costs (\$8,250,000) and postage (\$1,009,809) is \$9,259,809.

#### Capital Start-up costs

Depositories charge fees to depositors; all depositories charge about the same

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<sup>1</sup> Bureau of Labor Statistic rate for attorneys in scientific research and development services (23-1011 – Lawyers), plus 30% added for benefits and overhead (<https://www.bls.gov/oes/current/oes231011.htm>).

rates for their services. For example, the American Type Culture Collection (ATCC), one of the world's leading biological supply houses and recognized patent depositories, offers comprehensive patent services for \$2,500 per deposit. Any deposits from outside the US may have additional requirements, from other Federal Agencies, as a part of their importation process. The USPTO estimates that the total non-hour respondent cost burden in the form of capital start-up costs amounts to \$8,250,000 (3,300 respondents x \$2,500).

### Postage

Biological deposits are generally shipped to the depository "Domestic Overnight" by Federal Express (FedEx) and, since depositors are urged to supply frozen or freeze-dried material, it must be packed in dry ice. Dry ice itself is considered dangerous goods and requires special packaging. Additional FedEx special handling charges for inaccessible dangerous goods shipments of \$40 per shipment apply for temperature-sensitive biological materials and also for the dry ice. An average cost for shipping by FedEx "Domestic Overnight" is estimated to be \$90. If the shipment requires a pick-up by FedEx, there is an additional charge of \$6. Special packaging is also required for these shipments. The average cost of frozen infectious shippers is estimated to be \$170 per package of four for specimen shipments requiring refrigeration or dry ice. Therefore, the USPTO estimates the total postage costs average \$306 per shipment, for a cost to respondents of \$1,009,800 (3,300 respondents x \$306).

The USPTO estimates that it will receive from depositories 1 request for recognition. The USPTO estimates that the postage cost for a mailed submission of a request for recognition from a depository using a Priority Mail 2-day flat rate legal envelope is \$9.25. Therefore, the USPTO estimates that the total mailing costs for this information collection is \$9.00 per year.

#### **IV. Request for Comments**

The USPTO is soliciting public comments to:

- (a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected; and
- (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personally identifiable information (PII) in a comment, be aware that the entire comment—including PII—may be made publicly available at any time. While you may ask in your comment to withhold PII from public view, USPTO cannot guarantee that it will be able to do so.

**Justin Isaac,**

Information Collections Officer,

Office of the Chief Administrative Officer,

United States Patent and Trademark Office.



